REMARKS

Claims 1-17 are pending in the application. Claims 2, 10-12, and 15-16 are rejected for failing to particularly point out and distinctly claim the subject matter. Accordingly, independent claim 2 has been amended to better describe the invention thereby rendering the rejections of dependant claims 10-12 and 15-16 moot. Since the amendment places the application in condition for allowance, removes issues in the event of an appeal, and/or does not require further searching, entry is respectfully requested.

The Indefiniteness Rejection

Claims 2, 10-12, and 15-16 are rejected for failing to particularly point out and distinctly claim the subject matter. The Examiner contends that the phrase "characterized in that uridin-5'-monophosphate is concerned" renders the claim indefinite and unclear. Accordingly, independent claim 2 has been amended to read, "wherein uridine-5'-monophosphate is administered to a patient in need thereof." It follows that the scope of the amended claimed subject matter can clearly be determined by one having ordinary skill in the art. Hence, it is respectfully requested that the rejection of claims 2, 10-12, and 15-16 be withdrawn.

The Obviousness Rejection

Claims 1-17 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Connolly et al literature review (TiPS, 1999, Vol. 20, pp. 218-225). Connolly et al is cited for alleged teachings concerning the roles for the pyrimidine nucleoside uridine and its nucleotide derivatives in the regulation of some biological systems. Moreover, Connolly asserts broadly speculative suggestions regarding the possibility of therapeutic targets such as respiratory, circulatory, reproductive, and nervous systems, and the treatment of cancer and HIV infection.

The Examiner contends that since the few studies cited in Connolly et al represent a small number of compounds, the use of UMP would have been readily envisioned by one of ordinary skill in the art. While Connolly does only discuss

relatively few molecules, the studies cited in Connolly (specifically those relating in some way to the peripheral nervous system) at most implicate a role for nucleotides as neurotransmitters, ***but do NOT suggest a particular mechanism of action or implicate claimed molecules in neuroregeneration***. Connolly, at most, merely postulates a role for uridine (and NOT cytidine) as an inhibitory neuromodulator (p. 221, col. 1, ¶ 3).

Among the electrophysiological studies cited by Connolly, it was found that nucleotides (including CMP and UMP) altered the polarity in amphibian sympathetic ganglia and in rat superior cervical ganglia. These observations suggest that nucleotides may have roles as neurotransmitters, ***but did NOT implicate CMP or UMP involvement in nerve or muscle regeneration***. Conversely the Example of the application demonstrates (see page 7 of the present application), for the first time, the clinical usefulness in humans of short term treatment with a single pyrimidine and that the mechanism of action of the treatment with a single pyrimidine according to present invention is nerve regeneration. The mechanism of stimulating regeneration, as claimed in independent claim 1, occurs via synthesis of membrane phospholipids, such as sphingolipids and phosphatidylcholine. Connolly fails to teach or suggest stimulating regeneration by synthesis of membrane phospholipids. Hence, because Connolly only suggests roles as neurotransmitters, it would not have formed the basis for obviousness among individuals skilled in the art to use cytidine or uridine in a method and composition as claimed in independent claims 1 and 7 respectively.

Further, the Examiner draws attention to another study cited in Connolly that asserts that uridine dramatically promoted the recovery from the neural regeneration produced by diabetic neuropathy. This was an electrophysiological study that alleges improvement of motor and sensory responses in a small sample size (n=20) receiving treatment after 60, 120, and 180 day intervals. The study based its conclusions upon measurements in the small 120 day experimental group compared only to the 90 day control group (also n=20). Although the amplitudes of motor and sensory responses appeared improved in individuals that received UMP, ***this study also did not identify a***

mechanism for improvement, it did not measure nerve growth, nor did it implicate UMP or CMP as being involved in regeneration (CMP was not used in the study). Moreover, assertions are suspect at best due to shoddy experimental design, mainly small sample sizes.

The Examiner concedes that while Connolly et al may teach some therapeutic benefits of uridine and its nucleotides, it does so broadly. As suggested by the Examiner, the cited document only provides general information regarding possible effects of uridine on the nervous system. The studies cited in Connolly implicate a role for nucleotides as neurotransmitters, but do not suggest a particular mechanism of action. Moreover, Connolly et al fails to suggest any elements set forth in the claims. Connolly draws a general and speculative conclusion that UMP may prove therapeutic utility in treating neurodegenerative disorders, but does not teach or suggest how. The studies cited in Connolly only show electrophysiological changes in some nerve cells and at best suggest possible roles for nucleotides only as neurotransmitters. ***Nucleotides were not implicated in tissue regeneration***, nor was CMP tested in the diabetic neuropathy study. Therefore based on Connolly's teachings it would NOT have been obvious to an individual skilled in the art to use UMP or CMP to treat polyneuropathies, neuritides and/or myopathies as claimed.

Since the documents cited in the Connolly literature review do NOT teach or suggest the use of a composition of UMP or CMP to treat polyneuropathies, neuritides and/or myopathies, or method thereof, a skilled artisan would NOT have been motivated by alleged features of the Examiner's cited document. Therefore, it is respectfully requested that the obviousness rejection be withdrawn.

Petition for Extension of Time

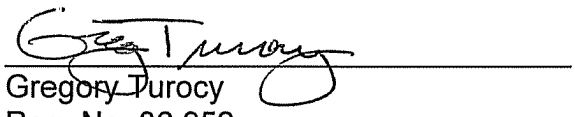
A request for a three month extension of time is hereby made (small entity status has been established). Payment is being made through the EFS electronic filing system.

In the event any fees are due in connection with this document, the Commissioner is authorized to charge those fees to Deposit Account No. 50-1063.

Should the Examiner believe a telephone interview would be helpful to expedite favorable prosecution, the Examiner is invited to contact applicant's undersigned representative at the telephone number listed below.

Respectfully submitted,

AMIN, TUROCY & CALVIN, LLP



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